

## REMARKS/ARGUMENTS

### Examiner's Interview Summary

On June 7, 2004, Examiner Marschel and the below listed attorney discussed the Final Office Action mailed on April 7, 2004. The issue of support for the subject matter cited as being New Matter was discussed, along with the citation error in which the Alajoki et al. reference was cited for both prior art rejections. The Examiner stated that he would revise and resend the Office Action, restarting the time period for response. In addition, the Examiner requested a Power of Attorney for the below listed attorney. An Associate Power of Attorney was submitted to the US Patent Office on June 11, 2004.

### New Matter

Claims 1-9, 13, 39-41, 43-46, 49, 50, 53, 54, 60, 61, 72-75, 77 and 81-85 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The Office Action asserted that these claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the Inventor(s), at the time the application was filed, had possession of the claimed invention. In particular, the Office Action asserts that the recitation of the spontaneous fluid transport of a fluid sample from the acquisition zone to the detection zone in claim 1 constitutes new matter, and that the cite in the Specification at page 18, lines 15-23 does not provide written support for this subject matter.

As set forth in the prior response submitted on January 21, 2004, support for the language changes in amended claim 1 was clearly defined in the specification, with the cite on page 18, lines 15-23 being just one example. Applicants direct the Examiner to page 24, lines 16-20, wherein it is stated that the channels of the detection article include an acquisition zone and a detection zone, and that the "channels 204 provide a means to wick or transport a liquid sample into the acquisition zone 210, between the acquisition zone 210 and the detection zone 220, and into the detection zone 220, by spontaneous" fluid transport, or capillary action, "throughout the length of the channels 204." [Specification, Page 24, Lines 16-20].

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The specification, drawings and originally filed claims provide a clear description of the present invention, which would have reasonably conveyed to one of skill in the relevant art that the Inventors had possession of the invention, as recited in previously submitted claim 1, at the time the application was filed. The above listed cite clearly shows the support for the language of claim 1. In addition, numerous instances of spontaneous fluid or liquid transport throughout the specification and original claims, coupled with the description and drawings of the channels including the acquisition zone and the detection zone and fluid flow between the two, clearly support the language as recited in this claim. Therefore, Applicants respectfully request withdrawal of the new matter rejection and allowance of claim 1. The claims dependent directly or indirectly from claim 1 are also allowable for at least the same reasons.

#### Prior Art

Claims 1-3, 5-7, 13, 39-41, 43-46, 53, 54, 60, 61, 72-75, 81 and 83-85 were rejected under 35 U.S.C. 102(e)(2) as being anticipated by Alajoki et al. (US 6,416,642). The Office Action stated that this rejection would still stand if the amended form of claim 1 were to ultimately be viewed as NOT containing NEW MATTER. The Office Action further stated that the placement of absorbent material into a channel qualifies as the structure and topography of the surface of the channels or the nature of the film surface, so as to influence spontaneous fluid transport in the channel.

Claims 1-7, 39-41, 43-46, 49, 50, 53, 54, 60, 61, 72-75, 81 and 83-85 were rejected under 35 U.S.C. 102(e)(2) as being anticipated by Christian (US 4,673,657). The Office Action also maintained this rejection even if the amended form of claim 1 were to ultimately be viewed to NOT contain NEW MATTER. The Office Action stated that there is no limitation as to what is meant by spontaneous fluid transport on page 18 of the specification which would negate the assertion that the solenoid roller squeezing a sample and forcing the fluid movement is not spontaneous fluid transport. The Office Action goes on to state that the roller practice changes the structure or topography of the channel and the nature of the film surface thus permits fluid flow under the roller pressure.

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In both of these rejections, the Office Action has stated that the cited references include all of the limitations of claim 1 after defining spontaneous fluid transport based on a few sentences on Page 18 of the specification and asserting that each reference teaches spontaneous fluid transport within this definition. Applicants strongly disagree with the definition and the characterization of the present invention made in the Office Action, and assert that, when defined correctly, neither cited reference teaches nor suggests the present invention as claimed.

Claim 1 recites a detection article comprising at least one polymeric fluid control film layer including an acquisition zone, a detection zone and at least one microstructured major surface including a plurality of microchannels therein. The microchannels are adapted to draw a fluid sample into the acquisition zone through openings in the microchannels, and to provide fluid flow of the fluid sample from the acquisition zone to the detection zone along the microchannels by spontaneous fluid transport. The detection zone includes at least one detection element that facilitates detection of a characteristic of the fluid sample within at least one microchannel of the detection zone.

The present invention is described thoroughly within the specification, including the drawings and claims as originally filed. In particular, a fluid control film is defined on Page 10, as well as being described in detail in the Summary and throughout Pages 11-24. The detection device of the claimed invention is formed from a fluid control film layer. In the discussion, the ability of the fluid control film to spontaneously transport fluid is described. The term "spontaneous" is well known in the art and has the dictionary definition of "being independent of external agencies; self acting," [Random House Webster's Unabridged Dictionary, Second Edition, Page 1843] or "developing without apparent external influence, force, cause, or treatment." [Merriam-Webster Online Dictionary, Item 5] These definitions are in accord with the use of the term and the explanation provided in the specification for the fluid control film's ability to spontaneously transport a liquid or fluid into the channels of the fluid control film and transport that liquid or fluid along the channels due to the channels themselves as formed within a surface of the film. The ability of the channels to spontaneously transport liquids or fluid may be influenced, i.e., increased or decreased, by

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modification of the structure of the channels or the nature of the film's surface. Such modification is described with respect to the film channels themselves and not to the use of external forces or agencies.

In the Alajoki et al. reference, absorbent material is added to induce wicking in the channel system of a microfluidic device. Such addition of material constitutes an external agency or external influence, force, cause or treatment. Without the added material, the microfluidic device and channel system does not draw a fluid sample into an acquisition zone through openings in the microchannels and provide fluid flow of the fluid sample from the acquisition zone to a detection zone along the microchannels by spontaneous fluid transport. Such addition of material does NOT modify the structure or topography of the channel itself, nor does it modify the nature of the film surface, but instead rests within the channel on top of the surface.

In Christian, a solenoid roller external to the device applies pressure and squeezes the fluid sample forcing fluid movement through the channels. This is clearly an external application of force causing fluid movement and does not qualify under any definition or interpretation as spontaneous fluid transport by the channels of the device. Therefore, neither Alajoiki et al. nor Christian anticipate or suggest the present invention as recited in claim 1, and claim 1 is allowable. The remaining rejected claims are allowable for at least the same reasons. Thus, Applicants respectfully request withdrawal of the rejections and allowance of all pending claims.

### CONCLUSION

All of the claims remaining in this application should now be seen to be in condition for allowance. The prompt issuance of a notice to that effect is respectfully solicited. If there are any remaining questions, the Examiner is requested to contact the undersigned at the number listed below.


No fee is believed to be necessary for the entry of this paper. Should any fee be required for entry of this paper, the Commissioner is authorized to charge the Faegre &

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Benson Deposit Account No. 06-0029 and in such event, is requested to notify us of the same.

Respectfully Submitted,

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